CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 75-139 / S-002, S-003

***Name*:** Ibuprofen Tablets USP, 200 mg

***Sponsor*:** LNK International, Inc.

***Approval Date*:** February 11, 2002

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-002, S-003

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Chemistry Reviews	X
Bioequivalence Review(s)	
Statistical Review(s)	
Microbiology Review	
Administrative Documents	
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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-002, S-003

APPROVAL LETTER

ANDA 75-139/S-002 & S-003

FEB 11 2002

LNK International, Inc.
Attention: Pankaj Chudgar
60 Arkay Drive
Hauppauge, NY 11788

Dear Sir:

This is in reference to your supplemental new drug applications dated June 27, 2001, submitted pursuant to section 505 (j) of the Federal Food, Drug, and Cosmetic Act for Ibuprofen Tablets USP, 200 mg.

Reference is also made to your amendment dated January 14, 2002.

The supplemental applications, submitted as "Prior Approval Supplements", provide for:

S-002 Labeling Revision

S-003 Control revision to include a second film coating, [redacted] Orange, to the tablets.

We have completed the review of these supplemental applications and they are approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

2-11-02

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 75-139
Division Files
Field Copy

Endorsements:

HFD-625/U.S. Atwal, Ph.D./2/4/02 2/7/02
HFD-625/D. Gill, Ph.D./2/5/02 2-8-02
HFD-617/R. Wu, Pharm. D./2/5/02 2/8/02
HFD-613/J. Barlow/ 2/8/02
HFD-613/J. Grace/ 2/9/2002

V:\FIRMSAM\LNK\LTRS&REV\75139S03.RV2
F/T by: DJ 2/6/02

SUPPLEMENT - APPROVABLE

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-002, S-003

LABELING

Original

Ibuprofen 200

CAPLETS

DO NOT USE IF THE IMPRINTED FOIL SEAL UNDER CAP IS BROKEN OR MISSING

12 FILM COATED ORANGE CAPLETS* 200 mg EACH

*Caplets (Capsule-Shaped Tablets)

SAVE BOX FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredient (in each orange tablet) — **Purpose**

Ibuprofen USP, 200 mg ..... Pain Reliever/ Fever Reducer

Warnings See box for complete warnings

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Alcohol Warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/ fever reducers. Ibuprofen may cause stomach bleeding.

Directions The smallest effective dose should be used. Take with food or milk if occasional or mild heartburn, upset stomach, or stomach pain occurs with use.

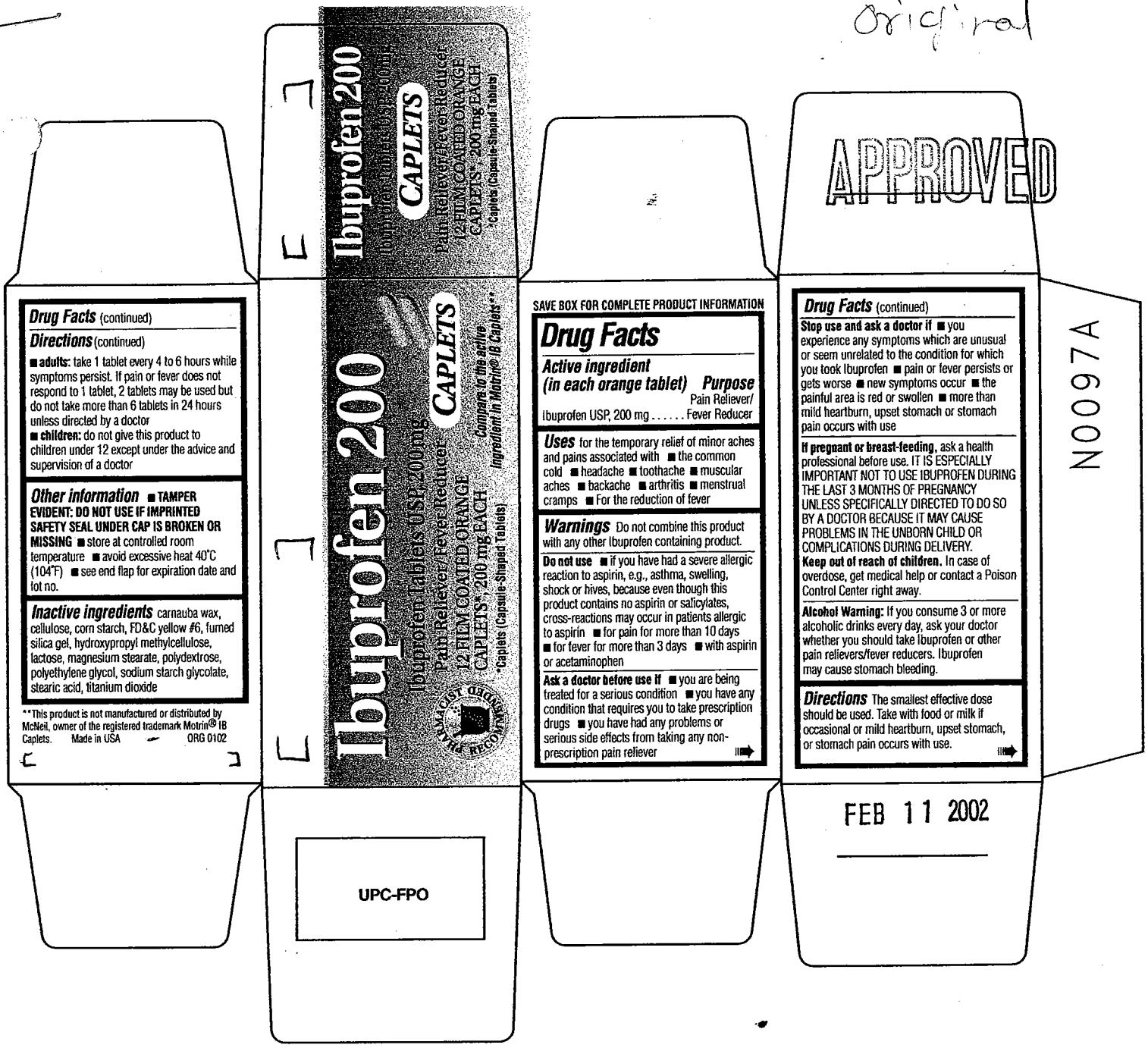
- **adults:** take 1 tablet every 4 to 6 hours while symptoms persist. If pain or fever does not respond to 1 tablet, 2 tablets may be used but do not take more than 6 tablets in 24 hours unless directed by a doctor
- **children:** do not give this product to children under 12 except under the advice and supervision of a doctor

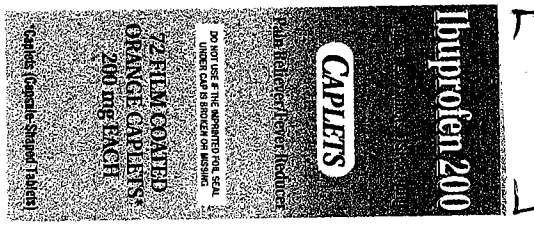
Other information ■ **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING** ■ store at controlled room temperature 15-30°C (59-86°F) ■ avoid excessive heat 40°C (104°F)

APPROVED

FEB 11 2002

Original


Ibuprofen 200
Ibuprofen Tablets USP, 200 mg
CAPLETS
Pain Reliever/Fever Reducer
12 FILM COATED ORANGE CAPLETS* 200 mg EACH
*Caplets (Capsule-Shaped Tablets)
Ibuprofen 200
Ibuprofen Tablets USP, 200 mg
CAPLETS
Pain Reliever/Fever Reducer
12 FILM COATED ORANGE CAPLETS*, 200 mg EACH
*Caplets (Capsule-Shaped Tablets)
Compare to the active ingredient in Motrin® IB Caplets**
PHARMACIST RECOMMENDED
Drug Facts (continued)
Directions (continued)
■ adults: take 1 tablet every 4 to 6 hours while symptoms persist. If pain or fever does not respond to 1 tablet, 2 tablets may be used but do not take more than 6 tablets in 24 hours unless directed by a doctor
■ children: do not give this product to children under 12 except under the advice and supervision of a doctor
Other information ■ TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING ■ store at controlled room temperature ■ avoid excessive heat 40°C (104°F) ■ see end flap for expiration date and lot no.
Inactive ingredients carnauba wax, cellulose, corn starch, FD&C yellow #6, fumed silica gel, hydroxypropyl methylcellulose, lactose, magnesium stearate, polydextrose, polyethylene glycol, sodium starch glycolate, stearic acid, titanium dioxide
**This product is not manufactured or distributed by McNeil, owner of the registered trademark Motrin® IB Caplets. Made in USA ORG 0102
UPC-FPO
SAVE BOX FOR COMPLETE PRODUCT INFORMATION
Drug Facts
Active ingredient (in each orange tablet) Purpose
Ibuprofen USP, 200 mg ..... Pain Reliever/ Fever Reducer
Uses for the temporary relief of minor aches and pains associated with ■ the common cold ■ headache ■ toothache ■ muscular aches ■ backache ■ arthritis ■ menstrual cramps ■ For the reduction of fever
Warnings Do not combine this product with any other ibuprofen containing product.
Do not use ■ if you have had a severe allergic reaction to aspirin, e.g., asthma, swelling, shock or hives, because even though this product contains no aspirin or salicylates, cross-reactions may occur in patients allergic to aspirin ■ for pain for more than 10 days ■ for fever for more than 3 days ■ with aspirin or acetaminophen
Ask a doctor before use if ■ you are being treated for a serious condition ■ you have any condition that requires you to take prescription drugs ■ you have had any problems or serious side effects from taking any non-prescription pain reliever
APPROVED
Drug Facts (continued)
Stop use and ask a doctor if ■ you experience any symptoms which are unusual or seem unrelated to the condition for which you took Ibuprofen ■ pain or fever persists or gets worse ■ new symptoms occur ■ the painful area is red or swollen ■ more than mild heartburn, upset stomach or stomach pain occurs with use
If pregnant or breast-feeding, ask a health professional before use. IT IS ESPECIALLY IMPORTANT NOT TO USE IBUPROFEN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY DIRECTED TO DO SO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
Alcohol Warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take Ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.
Directions The smallest effective dose should be used. Take with food or milk if occasional or mild heartburn, upset stomach, or stomach pain occurs with use.
N0097A
FEB 11 2002



Drug Facts

Active ingredient (in each orange tablet) — **Purpose**

Ibuprofen USP, 200 mg ..... Pain Reliever/Fever Reducer

Uses for the temporary relief of minor aches and pains associated with ■ the common cold ■ headache ■ toothache ■ muscular aches ■ backache ■ arthritis ■ menstrual cramps ■ For the reduction of fever

Warnings Do not combine this product with any other ibuprofen containing product.

Do not use ■ if you have had a severe allergic reaction to aspirin, e.g., asthma, swelling, shock or hives, because even though this product contains no aspirin or salicylates, cross-reactions may occur in patients allergic to aspirin ■ for pain for more than 10 days ■ for fever for more than 3 days ■ with aspirin or acetaminophen

Ask a doctor before use if ■ you are being treated for a serious condition ■ you have any condition that requires you to take prescription drugs ■ you have had any problems or serious side effects from taking any non-prescription pain reliever

Stop use and ask a doctor if ■ you experience any symptoms which are unusual or seem unrelated to the condition for which you took Ibuprofen ■ pain or fever persists or gets worse ■ new symptoms occur ■ the painful area is red or swollen ■ more than mild heartburn, upset stomach or stomach pain occurs with use

If pregnant or breast-feeding, ask a health professional before use. IT IS ESPECIALLY IMPORTANT NOT TO USE IBUPROFEN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY DIRECTED TO DO SO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Alcohol Warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take Ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.

Directions The smallest effective dose should be used. Take with food or milk if occasional or mild heartburn, upset stomach, or stomach pain occurs with use.

■ **adults:** take 1 tablet every 4 to 6 hours while symptoms persist. If pain or fever does not respond to 1 tablet, 2 tablets may be used but do not take more than 6 tablets in 24 hours unless directed by a doctor ■ **children:** do not give this product to children under 12 except under the advice and supervision of a doctor

Other information ■ **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING** ■ store at controlled room temperature ■ avoid excessive heat 40°C (104°F)

Inactive ingredients carnauba wax, cellulose, corn starch, FD&C yellow #6, fumed silica gel, hydroxypropyl methylcellulose, lactose, magnesium stearate, polydextrose, polyethylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

**This product is not manufactured or distributed by McNeil, owner of the registered trademark Motrin® IB Caplets. Made in USA ORG 0102 UPC-FPO

APPROVED
FEB 11 2002

Original

EB 11 2002

APPROVED

Drug Facts

Active ingredient (in each orange tablet) — **Purpose**

Ibuprofen USP, 200 mg ..... Pain Reliever/Fever Reducer

Uses for the temporary relief of minor aches and pains associated with ■ the common cold ■ headache ■ toothache ■ muscular aches ■ backache ■ arthritis ■ menstrual cramps ■ For the reduction of fever

Warnings Do not combine this product with any other Ibuprofen containing product.

Do not use ■ if you have had a severe allergic reaction to aspirin, e.g., asthma, swelling, shock or hives, because even though this product contains no aspirin or salicylates, cross-reactions may occur in patients allergic to aspirin ■ for pain for more than 10 days ■ for fever for more than 3 days ■ with aspirin or acetaminophen

Ask a doctor before use if ■ you are being treated for a serious condition ■ you have any condition that requires you to take prescription drugs ■ you have had any problems or serious side effects from taking any non-prescription pain reliever

Stop use and ask a doctor if ■ you experience any symptoms which are unusual or seem unrelated to the condition for which you took Ibuprofen ■ pain or fever persists or gets worse ■ new symptoms occur ■ the painful area is red or swollen ■ more than mild heartburn, upset stomach or stomach pain occurs with use

If pregnant or breast-feeding, ask a health professional before use. IT IS ESPECIALLY IMPORTANT NOT TO USE IBUPROFEN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY DIRECTED TO DO SO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Alcohol Warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take Ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.

Directions The smallest effective dose should be used. Take with food or milk if occasional or mild heartburn, upset stomach, or stomach pain occurs with use.

■ **adults:** take 1 tablet every 4 to 6 hours while symptoms persist. If pain or fever does not respond to 1 tablet, 2 tablets may be used but do not take more than 6 tablets in 24 hours unless directed by a doctor

■ **children:** do not give this product to children under 12 except under the advice and supervision of a doctor

Other information ■ **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING** ■ store at controlled room temperature ■ avoid excessive heat 40°C (104°F)

Inactive ingredients carnauba wax, cellulose, corn starch, FD&C yellow #6, fumed silica gel, hydroxypropyl methylcellulose, lactose, magnesium stearate, polydextrose, polyethylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

**This product is not manufactured or distributed by McNeil, owner of the registered trademark Motrin® IB

UPC-FPO

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-002, S-003

LABELING REVIEWS

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 75-139/S-002
Date of Submission: June 27, 2001
Applicant's Name: LNK International, Inc.
Established Name: Ibuprofen Tablets USP, 200 mg

Labeling Deficiencies:
GENERAL COMMENTS

Revise your labels and labeling to be in accordance with the revised labels and labeling for the reference listed drug, Motrin IB (NDA 19-012/S-024, approved October 2, 2000, to be in conformance with the OTC Labeling Final Rule 21 CFR 201.66). (See attached copy of this revised labeling)

RECOMMENDATIONS:

1. Inform the firm of the above comments.

2. Request the firm to revise their labels and labeling, then prepare and submit final printed container and carton labels.

FOR THE RECORD:

1. The firm did NOT utilize the most recently approved reference listed drug labeling for guidance. The most recently approved labeling was approved on October 2, 2000.

2. This supplement is a combined supplement SL-002 (Labeling revision) and SCS-003 (Control review). This combined supplement was submitted in reference to the addition of a colorant and a second film coating for this application.

Date of Review: 7/23/01 Date Submitted: June 27, 2001
Primary Reviewer: Jim Barlow Date: 8/31

Team Leader: John Grace Date: 9/4/2001

---

cc: ANDA
DUP/Division File
HFD-613/JBarlow/JGrace(no cc:)
V:\FIRMSAM\LNK\LTRS&REV\75139s2.naL
Review

Copy of Reference Listed Drug labeling removed.

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 75-139/S-002
Date of Submission: January 14, 2002
Applicant's Name: LNK International, Inc.
Established Name: Ibuprofen Tablets USP, 200 mg

Labeling Deficiencies:

1. **CONTAINER** – bottles of 12, 72 and 1000 tablets
   Satisfactory in **final print** as of the January 14, 2002 submission

2. **CARTON-** 12's
   Satisfactory in **final print** as of the January 14, 2002 submission

---

RECOMMENDATIONS:

1. Inform the firm of the above comments.

2. I informed the firm that they did NOT utilize the most recently approved labeling for this drug; Motrin IB, approved on October 2, 2000. I faxed a copy of this most recently approved labeling over to them. I requested that they make the necessary revisions and submit them as a separate CBE labeling supplement.

FOR THE RECORD:

1. The firm did NOT utilize the most recently approved reference listed drug labeling for guidance. The most recently approved labeling was approved on October 2, 2000. I informed the firm that they did NOT utilize the most recently approved labeling for this drug product and faxed a copy of this most recently approved labeling over to them. I requested that they make the necessary revisions and submit them as a separate CBE labeling supplement.

2. This supplement is a combined supplement SL-002 (Labeling revision) and SCS-003 (Control review). This combined supplement was submitted in reference to the addition of a colorant and a second film coating for this application.

Date of Review: 1/17/02 Date Submitted: 1/14/02
Primary Reviewer: Jim Barlow Date: 1/17/02

Team Leader: John Grace Date: 4/23/2002

---

cc: ANDA 75-139
DUP/Division File
HFD-613/JBarlow/JGrace(no cc:)
V:\FIRMSAM\LNK\LTRS&REV\75139s2.apl
Review

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-002, S-003

CHEMISTRY REVIEWS

OFFICE OF GENERIC DRUGS
ABBREVIATED NEW DRUG APPLICATION
CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

1. CHEMISTRY REVIEW NO. 1

2. ANDA # 75-139/S-003

3. NAME AND ADDRESS OF APPLICANT
LNK International, Inc.
Attention: Pankaj Chudgar
60 Arkay Drive
Hauppauge, NY 11788

4. LEGAL BASIS FOR SUBMISSION
Approved ANDA

5. SUPPLEMENT(s) S-003

6. PROPRIETARY NAME N/A

7. NONPROPRIETARY NAME
Ibuprofen Tablets, USP

8. SUPPLEMENT(s) PROVIDE(s) FOR:
Control revision to include a second film coating, [redacted], Orange, to the tablet.

9. AMENDMENTS AND OTHER DATES:
Date of Submission June 27, 2001

10. PHARMACOLOGICAL CATEGORY
Anti-inflammatory, Analgesic and Anti-pyretic

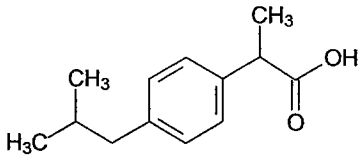
11. Rx or OTC
OTC

12. RELATED IND/NDA/DMF(s)
N/A

13. DOSAGE FORM
Tablet

14. POTENCY
200 mg

15. CHEMICAL NAME AND STRUCTURE
Ibuprofen. Benzeneacetic acid, □-methyl-4-(2-methylpropyl), (±)-. $C_{13}H_{18}O_2$. 206.29. 15687-21-1, 58560-75-1. Anti-inflammatory.



16. RECORDS AND REPORTS N/A

17. COMMENTS

The manufacturer of RLD has recently added an orange colored Motrin tablet. The basis for this supplement is the orange coated Motrin.

18. CONCLUSIONS AND RECOMMENDATIONS

Not Approvable, Minor

19. REVIEWER:

U.S. Atwal, Ph.D.

DATE COMPLETED

12/18/01

DATE REVISED

12/20/01

CC: ANDA 75-139
Division Files
Field Copy

Endorsements:

HFD-625/U.S. Atwal, Ph.D./12/20/01 N. Tabor for Atwal 12/21/01
HFD-625/D. Gill, Ph.D./12/20/01 John O. Franalis (for) 12/31/01
HFD-617/R. Wu, Pharm. D./12/21/01 R Wu 1/2/02

V:\FIRMSAM\LNK\LTRS&REV\75139S03.RV1
F/T by: DJ 12/21/01

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of trade secret and/or

confidential commercial

information from

CHEMISTRY REVIEW #1

37. <u>DMF CHECKLIST FOR ANDA #75-139/S-003</u>
Satisfactory

DMF #	DMF TYPE/SUBJECT/HOLDER	ACTION CODE	RESULT OF REVIEW	DATE REVIEW COMPLETED
—	III/[ ]	4		

ACTION CODES: (1) DMF Reviewed. Other codes indicate why the DMF was not reviewed, as follows:

(2) Type 1 DMF;

(3) Reviewed previously and no revision since last review;

(4) Sufficient information in application;

(5) Authority to reference not granted;

(6) DMF not available;

(7) Other (explain under"Comments").

[illegible signature] 12/31/01
Reviewer Signature Date

APPEARS THIS WAY
ON ORIGINAL

OFFICE OF GENERIC DRUGS
ABBREVIATED NEW DRUG APPLICATION
CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

1. CHEMISTRY REVIEW NO. 2

2. ANDA # 75-139/S-003

3. NAME AND ADDRESS OF APPLICANT
LNK International, Inc.
Attention: Pankaj Chudgar
60 Arkay Drive
Hauppauge, NY 11788

4. LEGAL BASIS FOR SUBMISSION
Approved ANDA

5. SUPPLEMENT(s) S-003

6. PROPRIETARY NAME N/A

7. NONPROPRIETARY NAME
Ibuprofen Tablets, USP

8. SUPPLEMENT(s) PROVIDE(s) FOR:
Control revision to include a second film coating, ———— Orange, to the tablet.

9. AMENDMENTS AND OTHER DATES:
Date of Submission June 27, 2001
Date of Minor Amendment January 14, 2002 (This Review)

10. PHARMACOLOGICAL CATEGORY
Anti-inflammatory, Analgesic and Anti-pyretic

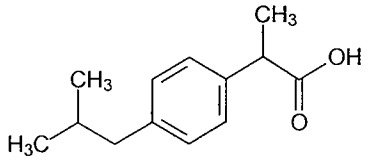
11. Rx or OTC
OTC

12. RELATED IND/NDA/DMF(s)
N/A

13. DOSAGE FORM
Tablet

14. POTENCY
200 mg

15. CHEMICAL NAME AND STRUCTURE
Ibuprofen. Benzeneacetic acid, -methyl-4-(2-methylpropyl), (±)-. $C_{13}H_{18}O_2$. 206.29. 15687-21-1, 58560-75-1. Anti-inflammatory.



16. RECORDS AND REPORTS N/A

17. COMMENTS
The manufacturer of RLD has recently added an orange colored Motrin tablet. The basis for this supplement is the orange coated Motrin.

18. CONCLUSIONS AND RECOMMENDATIONS
Approvable

19. REVIEWER: DATE COMPLETED
U.S. Atwal, Ph.D. 2/04/02

APPEARS THIS WAY
ON ORIGINAL

CC: ANDA 75-139
Division Files
Field Copy

Endorsements:
HFD-625/U.S. Atwal, Ph.D./ 2/4/2
HFD-625/D. Gill, Ph.D./ 2-5-02
HFD-617/R. Wu, Pharm. D./ 2/5/02

V:\FIRMSAM\LNK\LTRS&REV\75139S03.RV2
F/T by:

Redacted 6 page(s)

of trade secret and/or

confidential commercial

information from

CHEMISTRY REVIEW #2

37. DMF CHECKLIST FOR ANDA #75-139/S-003 REVIEW# 2
Satisfactory per review 1

DMF #	DMF TYPE/SUBJECT/HOLDER	ACTION CODE	RESULT OF REVIEW	DATE REVIEW COMPLETED
[redacted]	III/ [redacted]	4		

ACTION CODES: (1) DMF Reviewed. Other codes indicate why the DMF was not reviewed, as follows:

(2) Type 1 DMF;
(3) Reviewed previously and no revision since last review;
(4) Sufficient information in application;
(5) Authority to reference not granted;
(6) DMF not available;
(7) Other (explain under"Comments").

Reviewer Signature

2/4/2
Date

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-139 / S-002, S-003

CORRESPONDENCE

L N K INTERNATIONAL, INC.

OVER-THE-COUNTER PHARMACEUTICAL MANUFACTURERS

60 ARKAY DRIVE, HAUPPAUGE, LI, NY 11788 • (516) 435-3500

NDA NO. 75-139 REF. NO. SL-002
NDA SUPPL FOR Labeling Rev.

June 27, 2001

Office of Generic Drugs
CDER, FDA
8700 Standish Place
Metro Park North II
Rockville, MD 20855

NDA NO. 75-139 REF. NO. SCS-003
NDA SUPPL FOR Control Rev.

Supplement: Add Second Film Coating: ORANGE COLOR
ANDA 75-139; Ibuprofen USP, 200 mg Tablets

Dear Sir,

LNK requests a supplement to include a second film coating in our ANDA 75-139 Abbreviated New Drug Application (**Ibuprofen 200mg Orange Tablet code L-393** (white, RLD = Motrin). LNK has a companion ANDA (75-010) for Ibuprofen (brown, RLD = Advil; BE study 159-01-11013/14), which serves as reference for the Bioequivalent comparative dissolution study. McNeil Consumer Healthcare has recently added an orange colored Motrin tablet. The basis for this supplement is the orange coated Motrin. Supplement provides:

1. Component change information,
2. Executed test batch,
3. Proposed production batch,
4. Packaging configuration
5. Labeling
6. Stability information
7. Comparative dissolution profile
8. In-Vivo Bioequivalency Waiver request.

LNK is certain that the information is sufficient for a comprehensive review of the supplemental request. If there is need for additional information, please call me at (516) 543–3787.

CENTER FOR DRUG EVALUATION AND RESEARCH
RECD
JUN 2 8 2001
OGD

Sincerely,

Pankaj S. Chudgar
Vice President

ANDA 75-139/S-002 & S-003

JAN - 2 2002

LNK International, Inc.
Attention: Pankaj Chudgar
60 Arkay Drive
Hauppauge, NY 11788

Dear Sir:

This is in reference to your supplemental new drug applications dated June 27, 2001, submitted pursuant to section 505 (j) of the Federal Food, Drug, and Cosmetic Act for Ibuprofen Tablets USP, 200 mg.

The supplemental applications, submitted as "Prior Approval Supplements", provide for:

S-002 Labeling Revision

S-003 Control revision to include a second film coating, ——— Orange, to the tablets.

The supplemental application is deficient and, therefore, not approvable under Section 505 of the Act for the following reasons:

A. Chemistry Deficiencies:

1. [redacted]

2.

3.

4.

5.

6. [ ]

B. Labeling Deficiencies:

GENERAL COMMENTS
Revise your labels and labeling to be in accordance with the revised labels and labeling for the reference listed drug, Motrin IB (NDA 19-012/S-024, approved October 2, 2000, to be in conformance with the OTC Labeling Final Rule 21 CFR 201.66). (See attached copy of this revised labeling)

The file on this supplemental application is now closed. You are required to take an action described under 21 CFR 314.120 which will either amend or withdraw this supplemental application. Your amendment should respond to the deficiencies listed. A partial reply will not be considered for review, nor will the review clock be reactivated until all deficiencies have been addressed. The response to this letter will be considered a MINOR amendment and should be so designated in your cover letter. If you have substantial disagreement with our reasons for not approving this supplemental application, you may request an opportunity for a hearing.

Sincerely yours,

John O. Franchi (for)

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 75-139
Division Files
Field Copy

Endorsements:

HFD-625/U.S. Atwal, Ph.D./12/20/01 N. Talluri 12/31/01 for Atwal
HFD-625/D. Gill, Ph.D./12/20/01 John O. Franklin (for) 12/31/01
HFD-617/R. Wu, Pharm. D./12/21/01 RWu 1/2/02
HFD-613/J. Barlow/
HFD-613/J. Grace/ 1/2/2002

V:\FIRMSAM\LNK\LTRS&REV\75139S03.RV1
F/T by: DJ 12/21/01

SUPPLEMENT - NOT APPROVABLE - MINOR

APPEARS THIS WAY
ON ORIGINAL

Copy of Reference Listed Drug labeling removed.

ANDA 75-139 Ibuprofen USP 200 mg Film Coated Tablets
S-002 Labeling Revision
S-003 Control Revision

L N K INTERNATIONAL, INC.

Over-The-Counter Pharmaceutical Manufacturer

60 Arkay Drive, Hauppauge, LI, NY 11788

January 14, 2002

Rashmikant M. Patel, Ph. D.
Director
Division of Chemistry I
Office of Generic Drugs
CDER
Food and Drug Administration
8700 Standish Place
Rockville, MD 20855

SUPPL AMENDEMENT
SL-002
SCS-003 /AM.

FPL

MINOR AMENDMENT
Supplement: An Alternate Film Coating: COLOR
ANDA 75-139; Ibuprofen USP, 200 mg Tablets
Bioequivalence Data included

Dear Dr. Patel:

LNK is responding in full to the Minor Deficiency Letter dated January 2, 2002. LNK had submitted a supplement for a second color (***Orange***) in our approved Abbreviated New Drug Application , ANDA 75-139, **Ibuprofen, USP, 200mg White Tablet, code L393** (white, RLD = Motrin). The Agency has indicated that this submission includes two supplements, S-002 for a Labeling Revision and S-003 for Control Revision. LNK has a companion ANDA (75-010) for Ibuprofen (brown, RLD = Advil; BE study 159-01-11013/14), which serves as reference for the comparative dissolution study.

Chemistry Deficiencies:

1. [redacted]
2.
3.
4.
5.
6.

Labeling Deficiencies:

1. Revise labels and labeling to conform to the OTC Labeling Final Rule 21 CFR 201.66.

LNK is certain that the information is sufficient for a comprehensive review of the supplemental request. If there is need for additional information, please call me at (631) 543 – 3787.

CENTER FOR DRUG EVALUATION AND RESEARCH
JAN 15 2002

Sincerely,

Pankaj S. Chudgar
Vice President

PSC/dju
Enc.

Telephone: (631) 435-3500 - Facsimile: (631) 435-3542 - E-Mail: lnk01@ix.netcom.com